

## REMARKS

The Non-Final Office Action has been carefully reviewed and the following remarks are made in light of the Action. Entry and consideration of the foregoing amendments is respectfully requested.

Claims 16, 18 and 19 have been amended as suggested by the Examiner in the Non-Final Office Action. Claims 30 and 31 have been newly added. Claim 30 is directed to alfalfa varieties of the present invention, wherein such alfalfa varieties comprise “‘French’ type alfalfa germplasm”. Support for ‘French’ as used in the context of the present invention can be found throughout the as-filed application. See for example, page 4, line 17 to page 5, line 2; page 25, line 15 to page 26, line 10; page 30, lines 3 to page 31, line 9; page 35, lines 16 to page 36, line 23; and page 40, line 13 to page 41, line 20. Claim 31 depends from claim 30 and further limits the ‘French’ germplasm to “‘Flemish’ type alfalfa germplasm”. Support for ‘Flemish’ can be found throughout the as-filed application. See for example, page 4, line 17 to page 5, line 2. Support for the term “germplasm” can be found throughout the as-filed specification. See, for example, ‘Field of the Invention’, page 1, lines 11-14. No new matter has been added by way of these amendments.

## RESPONSE

### I. Claim Objections

Claims 16, 18 and 19 are objected to because of informalities. Appropriate correction has been made as suggested by the Examiner. Reconsideration and withdraw of the objection in view of these amendments and remarks herein are respectfully requested.

### II. Claim Rejections – 35 USC § 112, First Paragraph – Written Description

Claims 2-4 and 6-19 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Office Action alleges that “Applicants have possession of a narrow genetic base and is broadly claiming the phenotype. Applicants are in possession of a narrow invention limited to particular lines, however, they are broadly claiming every alfalfa plant that has the phenotype of their lines even though no analysis as to which genes are involved or how the traits are expressed is given. This

is paramount to selecting a seed line for high yield and then claiming every seed line that has high yield, regardless of how they are made. It would be like selecting a seed line for its color and then claiming every seed that happens to have that characteristic regardless of how it was derived” (Detailed Action, page 5, first paragraph, underlining added).

As an initial matter, Applicants address the Examiner’s statement as underlined immediately above. Applicants agree that the instant invention could be compared to inventing and patenting lines with novel and non-obvious characteristics such as high yield, color or other characteristics. In fact, U.S. patents which have issued to exactly the types of inventions the Examiner now seems to suggest are unpatentable. See, for example, U.S. Patent No. 5,602,313 which claims:

1. A soybean plant having pink flowers and uniform pigmentation throughout each petal as a distinguishing phenotype.

Thus, the US PTO did and does issue claims to seed lines (e.g., any “soybean plant”) with particular characteristics, such as color (e.g., “having pink flowers”), regardless of how they are developed. Many additional such examples, including those involving plant yield, can be found by searching the US PTO’s Patent Full-Text and Image Database. Thus, Applicants presently claimed invention clearly falls within the standards set by the US PTO for patentable inventions of similar type and scope.

Applicants respectfully note that they are not claiming just any *Medicago sativa* alfalfa plant with faster recovery and more erect stems, but rather are claiming *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to specific commercial check varieties, wherein such checks were the best commercial check varieties available at the time of the present invention and the varieties are compared under the same growing conditions and growth stages.

*Vas-Cath Inc. v. Mahurkar*, which is relied upon by the Examiner to support this rejection, held that “to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.” *Id*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See, also, the U.S. Patent

& Trademark Office's ("US PTO") position on the teachings of this case as provided at M.P.E.P. § 2163.02. As discussed in great detail in the Amendment and Response Under 37 C.F.R. § 1.111, filed December 12, 2007, and in the Response to the first Non-Final Office Action, filed June 21, 2006, Applicants have clearly met the standard for the written description requirement set forth in *Vas-Cath Inc. v. Mahurkar*. The presently pending claims clearly set forth exactly how a potential infringer can determine whether a particular *Medicago sativa* alfalfa variety falls within the metes and bounds of the claimed invention, wherein the claimed elements of those metes and bounds are clearly and explicitly set forth in the as-filed specification.

In addition, the as-filed specification provides detailed written descriptions of the development of at least four very different and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic background, wherein each of these varieties clearly meet the limitations of the claims (see, for example, Example 3, pages 25-45). The Examiner states that "[A]lfalfa variety 'CW 85029' does not appear to have the claimed traits" (Detailed Action, page 4, lines 4-5). Applicants traverse the Examiner's statement. Tables 1, 3 and 4 clearly demonstrate that 'CW 85029' has 8% or greater recovery after spring green-up or after harvest when compared to one or more of the commercial check varieties listed in the claims. Furthermore, Tables 7a, 7b, 7e, 7f and 7g all demonstrate that 'CW 85029' has 15% or greater more erect stems at late (i.e., 75%) bloom when compared to one or more of those same commercial check varieties. The "zeros" for 'CW 85029' in the last columns of Tables 6a and 6b are there because 'CW 85029' was chosen as the variety by which all of the other varieties were compared since it was the best of all of the varieties for erect stems. Finally, a summary of the standability and recovery traits for each of the four varieties, including 'CW 85029', as compared to two of the commercial check varieties was provided to the Examiner at page 15 of the 'AMENDMENT AND RESPONSE Under 37 C.F.R. § 1.111', which was filed in this application on June 21, 2006. That summary clearly shows that 'CW 85029' and the other three exemplary varieties meet the limitations of independent claim 15. For at least these reasons, Applicants maintain that 'CW 85029' is also an exemplary line for the presently claimed alfalfa varieties.

As Applicants have repeatedly asserted during the course of prosecuting the presently pending claims, anyone skilled in the art of alfalfa variety development can follow the procedures described in the as-filed specification to develop additional varieties which fall within

the limitations of the claimed genus of alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late (i.e., 75% bloom) when compared to the specific adapted check alfalfa varieties as set forth in the claims. Alternatively, one skilled in the art can use any of Applicant's inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations. The as-filed specification clearly comprehends such uses of the exemplified varieties. See, e.g., original claim 24, previously canceled. In fact, the attached Declaration by Dr. Johnson and the accompanying Exhibit I ("the Johnson Declaration") clearly demonstrates that Applicants have done exactly this (i.e., developed additional *Medicago sativa* alfalfa varieties with the claimed traits by using the exemplary, deposited varieties as a source of genetic material in the breeding regime leading to such additional varieties). The Johnson Declaration provides evidence that Applicants have used one or more of each of the four exemplified varieties to develop at least three additional alfalfa varieties which meet the limitations of the alfalfa varieties claimed in independent claim 15. Thus, anyone skilled in the art of plant breeding can utilize one or more of the exemplified, deposited alfalfa varieties developed by the inventors to produce additional alfalfa varieties with the new and inventive traits now claimed.

Applicants believe that it is a clear error for the Examiner to maintain this rejection at least because the as-filed specification conveys the invention to the public with reasonable clarity; Applicants' have demonstrated they were clearly in possession of the invention at the time of filing (at least by the deposit of seed for four diverse, exemplified varieties); the as-filed specification demonstrates that Applicants had multiple examples of their claimed subject matter in hand at the time of filing; and Applicants have demonstrated (via the Johnson Declaration) that the exemplified, deposited varieties have been successfully utilized according to the as-filed specification and breeding skills well known to those in the art to develop additional varieties which meet the claim limitations. The Examiner is respectfully requested to withdraw this rejection and issue the pending claims.

### III. Claim Rejections – 35 USC § 112, First Paragraph – Enablement

Claims 2-4 and 6-19 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

The rejection states that “a deposit is required for enablement purposes” (Non-Final Office Action, page 6, first paragraph). In response, Applicants hereby state the following regarding ATCC Deposit Nos. PTA-5346, PTA-5347, PTA-5348 and PTA-5349:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of the deposit showed that the deposited samples were viable; and
- (e) the deposit will be replaced if it should ever become inviable.

In addition, the Office Action alleges that “[I]t is unclear how one skilled in the art would be able to use Applicant’s specification to make and use the claimed invention when said invention is produced using uncharacterized material” and “[T]his lack of guidance would lead to undue experimentation for one skilled in the art to determine which 1,382 French varieties would possess the claimed characteristics that would be used in the method disclosed in the specification to produce the claimed invention”.

First, Applicants note that “[T]he examiner’s analysis must consider all of the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole” (M.P.E.P. 2164.01(a), citing *In re Wands* 858 F.2d 737, 740 8 USPQ2d at 1404, 1407). The Examiner’s rejection does not meet this standard.

Alfalfa breeding is a predictable art where, like here, Applicants have provided a clear and detailed plant breeding roadmap to accomplishing the claimed invention and deposited germplasm that provides the claimed traits. Surely, in view of Applicants’ disclosure, the claimed invention is predictable and the Examiner’s rejection is a clear error.

The specification clearly teaches that the instant claimed invention is an advancement in the art of breeding alfalfa for improved standability. See, for example, page 10, lines 18-20:

Prior to the instant invention, the standability differences between commercial alfalfa varieties has been so small that most alfalfa breeders do not even rate their varieties for this important trait.

The Examiner relies on Bouton as teaching that the “[collection and development of parents] is one of the most important decisions in the breeding program because the end product will only be as good as the parents which originally went into the process”. Applicants agree and in the originally-filed specification provided a detailed description of the parental lines that went into forming each of the four diverse, exemplary alfalfa varieties of the presently claimed invention. See, for example, page 25, lines 4-13, for a description of the parental lines used to produce ‘CW 75046’. Similar detailed parental line descriptions are provided for the parents of the other three varieties at page 29, line 14 – page 30, line 2 for ‘CW 83201’; page 35, lines 8-15 for ‘CW 85029’; and page 40, lines 3-12 for ‘CW 95026’. Newly presented claims 30 and 31 are directed to the inventive alfalfa varieties of the present invention wherein those varieties comprise “‘French’ type alfalfa germplasm” (claim 30), including “‘Flemish’ type alfalfa germplasm” (claim 31).

Applicants maintain, however, that the exact genetic, morphological and/or physiological characteristics of the parents are not directly relevant to the claimed invention given that Applicants have demonstrated that the disclosed methods were used to develop at least four different, distinct *Medicago sativa* alfalfa varieties each derived from a diverse parental background and each possessing the claimed traits. The as-filed specification provides detailed descriptions of the breeding process used to develop each of the four diverse, exemplary alfalfa varieties. See, for example, page 25, line 14 – page 26, lines 26 (‘CW 75046’); page 30, line 3 – page 31, line 25 (‘CW 83201’); page 35, line 16 – page 37, line 8 (“CW 85029”); and page 40, line 13 – page 42, line 8 (‘CW 95026’). Furthermore, as set forth in the attached Johnson Declaration, the deposited varieties were used to develop at least three more alfalfa varieties with the claimed traits.

The Examiner relies upon a 1977 article by Barnes *et al.* to support his conclusion that “the development of improved alfalfa varieties is unpredictable” for an alfalfa breeding invention filed in 2002. Barnes *et al.* state that “alfalfa is a recent introduction to North America” (Introduction, page 2, first column, second paragraph). Applicants fail to see the relevance in 2002 of a review article over 3 decades old which discusses the state of alfalfa breeding in the

1970's and earlier. In fact, this article provides evidence of the long-felt need and unexpected results of the present invention. See, e.g., where Barnes *et al.* discuss "characteristics needed in alfalfa varieties," which include "development of alfalfas with . . . use in pastures and ranges" (page 14). The very purpose of the present invention was to improve the recovery and erectness of alfalfa plants grown in the field. By the time the American Society of Agronomy published Monograph No. 29, 'Alfalfa and Alfalfa Improvement' in 1988 (only about a decade later), things had already changed. For example, in this 1988 Monograph, Barnes *et al.*<sup>1</sup> (*Highlights in the USA and Canada*, Chapter 1, pages 1-24; copy provided previously) discuss the many advances being made in alfalfa breeding, stating that "[A]n impressive amount of basic information essential to the future of alfalfa improvement was produced from 1975 to 1985" (page 5). It is certainly not hard to understand that even more gains have been made in the nearly two additional decades between 1985 and the filing of the instant application in 2002.

The Examiner next relies upon Julier *et al.* as teaching that "within-population variation can hinder the rate of improvement for polygenic traits, including lodging" (Non-Final Office Action, page 8, second to last paragraph). For their study, Julier *et al.* purposely chose to use cultivars that "represent a wide range of genetic variation and different eras of breeding" (page 365, column 2, Materials and Methods, first paragraph) so that they could optimize within-population variation. Therefore, it is not surprising that they subsequently obtained a fairly high level of within-population variation in the subsequent populations derived from these cultivars.

The publications cited by the Examiner do not detract from the fact that Applicants have demonstrated that alfalfa varieties with the claimed phenotypic characteristics can be developed using the breeding methods and germplasm set forth in the as-filed specification. Furthermore, Applicants have deposited seed of four exemplary alfalfa varieties developed using such procedures wherein each of these deposited varieties have the claimed phenotypical characteristics and provided evidence via the attached Johnson Declaration of the development of three additional alfalfa varieties using the methods and germplasm set forth in the as-filed application.

What is important is that Applicants have provided the necessary direction for one skilled in the alfalfa breeding arts to develop further *Medicago sativa* alfalfa varieties with the claimed

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<sup>1</sup> Yes, this is the very same "D. K. Barnes" that wrote the 1977 article relied upon by the Examiner.

characteristics. Furthermore, one skilled in the art can use the exemplary alfalfa varieties of the present invention to produce additional varieties with the claimed traits, as demonstrated in the Johnson Declaration.

Also, Applicants have newly added claim 30 which requires that the claimed alfalfa varieties comprise “‘French’ type alfalfa germplasm”. Newly added claim 31, which depends from claim 30, specifies that the ‘French’ type alfalfa germplasm be “‘Flemish’ type alfalfa germplasm”. The as-filed specification demonstrates that the exemplified alfalfa varieties of the present invention comprise ‘French’ type alfalfa germplasm, including ‘Flemish’ type alfalfa germplasm.

The Examiner is respectfully requested to withdraw this rejection and issue the pending claims.

#### IV. Claim Rejections – 35 USC § 103

Claims 2-4 and 6-19 are newly rejected under 35 USC § 103(a) as allegedly being unpatentable over Cluff et al (U.S. Patent No. 6,143,951 , November 7, 2000) in view of Bouton et al (Standard tests to characterize alfalfa cultivars, Intensive grazing A-8 August 1998) and Bolanos-Aguilar et al (Crop Sci. 42: 45-50, January/February 2002).

Applicants traverse this rejection and assert that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. “To establish *prima facie* case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art” (M.P.E.P. § 2143.03).

The Examiner asserts that “Cluff et al. teach a *Medicago sativa* alfalfa line, WL-C290, that has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38)”. The two lines of text in Cluff *et al.* cited by the Examiner state that WL-C290 has “Very fast recovery after harvest and excellent standability under sprinkler irrigation.” As alluded to by the Examiner, Cluff *et al.* provide no experimental data or evidence to support this statement.

Applicants previously submitted a Declaration Under 37 C.F.R. § 1.132 by Dr. Jonathan M. Reich (“the Reich Declaration”), an inventor of the present invention and an officer of the assignor. The Reich Declaration provides experimental data to definitively demonstrate that

‘WL-C290’ “is **susceptible** to lodging under sprinkler irrigation” (line spanning pages 2-3; emphasis added). As discussed in the Reich Declaration this “**susceptible**” rating for ‘WL-C290’ is based on the ‘Standability Expression (Lodging Resistance)’ industry standards as established by the North American Alfalfa Improvement Conference (“NAAIC”). The Non-Final Office Action fails to even acknowledge the Reich Declaration even though it demonstrates that Cluff *et al.* does not qualify as applicable prior art to the pending claims.

Also attached to the Reich Declaration are the Association of Official Seed Certifying Agencies (“AOSCA”) summary pages for the original certification of the alfalfa variety ‘C-290’ and the amendment for ‘C-290’ when it was re-named as ‘WL 711 WF’. As stated in the Reich Declaration “the breeding history for ‘WL-C290’ as described in these documents does not reference either selection for standability or any measure of standability.”

Based on the lack of any experimental data to support the assertions regarding the standability of ‘WL-C290’ in the Cluff *et al.* patent cited by the Examiner, the complete lack of any support for their assertions in the AOSCA descriptions of ‘WL-C290’, and most importantly in view of the evidence in the Reich Declaration clearly demonstrating that ‘WL-C290’ is susceptible to lodging even under less-than-complete-lodging growing conditions, the Cluff *et al.* reference cannot be prior art to the present invention under 35 U.S.C. § 103. In fact, Cluff *et al.* teaches away from the presently claimed invention.

In an attempt to bolster his argument in view of the lack of any relevant data in the Cluff *et al.* reference, the Examiner relies upon Bouton *et al.* (1998) to teach “measuring plant heights after harvesting” and states “it would have been obvious to one of ordinary skill in the art that other formulas can also be used to select an alfalfa variety” with the novel characteristics of the alfalfa plants of the instant invention. Bouton *et al.* merely provides guidance on measuring percent survival of alfalfa plants following grazing. Applicants fail to understand how this teaching meaningfully relates to the greater faster recovery after spring green-up or harvest as set forth for the claimed varieties of the present invention. Bouton *et al.* clearly falls far short of making up for the deficiencies of Cluff *et al.* to teach the claimed alfalfa plants of the present invention, particularly in view of the Reich Declaration showing that Cluff *et al.* actually teaches away from the claimed invention.

Next, the Examiner relies upon Bolanos-Aguilar et al. as teaching “a lodging scale from 1 (no lodging) to 5 (fully lodged)” and that lodging has a number of undesirable characteristics. Applicants agree that lodging has a number of undesirable characteristics and that is one of the reasons for the present invention – to reduce that undesirable lodging and this is reflected in the claims themselves. Clearly this reference also fails miserably to address any of the deficiencies of the Cluff *et al.* reference, particularly in view of the Reich Declaration.

In addition, in absence of the present invention, there is no suggestion to combine the teaching of Bouton *et al.* and Bolanos-Aguilar *et al.* with Cluff *et al.* Thus, it would have not been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the cited references. The Examiner is clearly using impermissible hindsight to combine the cited references to cobble together this obviousness rejection.

For all reasons described above, the Examiner is respectfully requested to withdraw this rejection and issue the pending claims for the reasons described above.

#### V. Claim Rejections – 35 USC § 102/103

Claims 2-4 and 6-19 stand rejected under 35 USC § 102(b) as allegedly being anticipated by or, in the alternative, under 35 USC § 103(a) as obvious over Cluff et al (U.S. Patent No. 6,143,951 , November 7, 2000).

As discussed above, Applicants provided the Examiner with a Declaration Under 37 C.F.R. § 1.132 by Dr. Jonathan M. Reich (“the Reich Declaration”), an inventor of the present invention and an officer of the assignor. The Reich Declaration provides experimental data to definitively demonstrate that ‘WL-C290’ “**is susceptible** to lodging **under sprinkler irrigation**” (line spanning pages 2-3; emphasis added). The data provided in the Reich Declaration definitively showed that improved alfalfa variety ‘CW 95026’ of the instant invention had significantly ( $P<0.05$ ) more resistance to lodging (90% erect stems) than did ‘WL-C290’ (40% erect stems). As discussed in the Reich Declaration this “**susceptible**” rating for ‘WL-C290’ is based on the ‘Standability Expression (Lodging Resistance)’ industry standards as established by the North American Alfalfa Improvement Conference (“NAAIC”). Clearly, this data demonstrates that ‘WL-C290’ does not have “excellent standability under sprinkler irrigation” when compared to the improved varieties of the instant invention.

Despite the fact that Cluff et al. specifically assert that WL-C290 has “excellent standability under sprinkler irrigation” and Applicants provided experimental evidence that the improved varieties of the instant invention have far superior standability under exactly the same growing conditions, the Reich Declaration is not even addressed in the Non-Final Office Action despite having been earlier supplied to the US PTO in this same application.

Applicants provided evidence to refute the assertions of the cited reference wherein such evidence was exactly on point to the teaching of the cited reference (i.e., lodging under irrigation conditions). One suspects that if Applicants had provided experimental evidence from non-irrigated plots that the Examiner would have stated that this evidence was not commensurate with the teachings applied. Applicants provided the evidence they did to forestall that very conclusion by the Examiner.

The specification itself teaches that the “improved standability of the alfalfa plants of the instant invention is even more useful when weather conditions are such that presently-available alfalfa varieties would typically lodge” (page 10, lines 18-20). Irrigation is one such “weather condition” (or at least an excellent mimic of heavy rains and waterlogged soils) and Applicants have demonstrated that the cited prior art fails to anticipate or even render obvious the instant claimed invention. Actually, the prior art relied upon by the Examiner strongly supports the patentability of the instant claimed invention. Applicants have demonstrated “that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance” when considered in view of the cited prior art. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992; M.P.E.P. § 716.02(b)). The Examiner has made a clear error by discounting the experimental evidence provided in the Reich Declaration filed with the Response to the Non-Final Office Action mailed June 12, 2007.

Thus, the Examiner is respectfully requested to withdraw this rejection and issue the pending claims.

### CONCLUSION

The Examiner is invited to contact the undersigned if necessary to advance prosecution of this application.

Applicants look forward to allowance of the pending claims or appealing this to the Board of Patent Appeals and Interferences for their consideration of Applicants' responses to each of the rejections, as discussed above.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

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